UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

TAMARA J. TOWNSEND, Plaintiff v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants	Case No.: 2:20-cv-01984-APG-DJA **Order Granting in Part Motion to Exclude General Causation Opinions of Dr. Jeppson** [ECF No. 71-1]

This case is one of thousands that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. That court conducted the MDL litigation in waves, with this case being in wave 12. The case was transferred to this court from the MDL court with several motions pending, including plaintiff Tamara Townsend's motion to limit the general causation opinions of the defendants' expert, Dr. Peter Jeppson. Townsend contends Jeppson is not qualified to render opinions about whether the warnings in the defendants' instructions for use (IFU) were adequate. The defendants oppose. The parties are familiar with the facts, so I do not repeat them here except where necessary. I grant the motion in part.

I. ANALYSIS

I adopt Judge Goodwin's prior articulation of the standard for reviewing motions challenging expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701-02 (S.D. W. Va. 2014).

Townsend argues Dr. Jeppson is not qualified to render expert opinions on the adequacy of the risk information contained in the IFU because he has no experience drafting an IFU, has never designed a medical device, and is not an expert on FDA regulations. Townsend also argues that Dr. Jeppson's opinions are unreliable because he admitted he does not know what the defendants knew about the risks associated with the mesh devices when they prepared their warnings, so he cannot opine on whether the disclosures were timely and adequate. Finally, Townsend argues that Dr. Jeppson should be precluded from testifying because he could not identify the predicate device for the TVT, TVT-O, and TVT-Abbrevo, so he lacks an understanding of the devices' regulatory and labeling history.

The defendants respond that Dr. Jeppson is qualified to opine on the risks and benefits of the devices and compare them with what was provided in the IFUs.[1] They also argue that Dr. Jeppson is qualified to testify about the risks that were commonly known to urogynecologists performing mesh surgeries. Finally, the defendants argue that Dr. Jeppson need not know the entire regulatory history for the TVT line of products to testify and that Townsend may cross examine him on this issue.

Dr. Jeppson opines that "the TVT, TVT-O, and TVT-Abbrevo IFUs provided appropriate information for surgeons to be able to use the devices safely" because they "included information regarding the indications for use of the devices, contraindications, . . . instructions on how to implant the devices," and "warnings and potential adverse reactions." ECF No. 71-1 at 23. He also opines that the IFU "does not need to contain information regarding risks that are not

[1] The defendants also contended that the motion was untimely for wave 10 plaintiffs. Townsend is a wave 12 plaintiff. In their notice adopting the prior wave briefing, the defendants did not indicate whether the timeliness argument applies to the wave 12 plaintiffs. I therefore do not consider this argument.

evidence-based, clinically significant or information on risks that are commonly known by gynecologists, urologists, or urogynecologists." *Id.* at 23-24. He contends that due to the training these practitioners receive, they would already be readily familiar with the risks and complications associated with urogynecological surgeries. *Id.* at 23.

"While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016); *see also Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 551 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014) (excluding a physician opinion on what information a product manufacturer should have included in its directions for use because the doctor never drafted a warning and had no experience with warnings beyond that of physicians in general). Dr. Jeppson does not have such expertise. *See* ECF No. 71-1 at 68. Consequently, he may not opine on whether the IFUs are "appropriate" or whether they "do[] not need to contain information" about risks. However, as an experienced urogynecologist, he may testify about the risks commonly known to urogynecologists and whether those risks appear in the IFUs. At what point those risks appeared in the IFUs in relation to the defendants' knowledge of those risks and the significance of Dr. Jeppson's awareness of the TVT line's predecessor device are matters for cross examination.

II. CONCLUSION

I THEREFORE ORDER that the plaintiff's motion to limit the general causation opinions of Dr. Peter Jeppson **(ECF No. 71-1) is GRANTED in part**. Dr. Jeppson may not testify about whether the information in the instructions for use was "appropriate" or that the

instructions for use "do not need to contain" risk information. However, he may testify about the risks of implanting mesh and whether those risks appear in the instructions for use.

DATED this 8th day of April, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE